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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,417	02/19/2004	Nadine Carozzi	045600/274146	6391

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,417	CAROZZI ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,19,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,19,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-11, 19 and 22-23 are pending.

2. The rejection of claims 1-11, 19 and 22-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding proteins with 95% identity to SEQ ID NO:2, host cells, plants, plant cells and seeds comprising them, and method of using them to make SEQ ID NO:2, does not reasonably provide enablement for nucleic acids encoding pesticidal protein with 90% identity to SEQ ID NO:2, nucleic acids with 95% or 90% identity to SEQ ID NO:1, host cells, plants, plant cells and seeds comprising them, and method of using them to make a pesticidal protein with 90% identity to SEQ ID NO:2 and a pesticidal protein encoded by a nucleic acid with 95% or 90% identity to SEQ ID NO:1 is withdrawn in light of Applicant's amendment of the claims.

3. The rejection of claims 1-11, 19 and 22-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicant's amendment of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Dov et al (1996, Appl. Environ. Microbiol., 62:3140-3145) in view of Carlton et al (1985, Mol.

Biol. Microb. Differ., Proc. Intl. Spore Conf., 9th, Meeting date 1984, pages 246-252; Ed. Hoch et al, Am.Soc. Microbiol., Washington, DC) and taken with the evidence of Applicant's response to the Request for Information under 37 CFR 1.105.

The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 August 2009, as applied to claims 1, 4-7, 24 and 27. Applicant's arguments filed 23 October 2009 have been fully considered but they are not persuasive.

Applicant's response to the Request for Information under 37 CFR 1.105, filed 17 March 2009, indicate that the bacterial strain from which SEQ ID NO:1-4 were isolated is HD536, and available from the USDA.

The claims are drawn to a nucleic acid encoding a toxin comprising SEQ ID NO:2.

Ben-Dov et al teach cloning of delta-endotoxin genes from a *Bacillus thuringiensis* plasmid (pg 3141. left column, to pg 3143, right column, paragraph 3). The genes were cloned in vectors that encode a selectable-marker protein heterologous to the endotoxin, and these clones were grown in an E. coli host cell (pg 3140, right column, paragraph 2). Ben-Dov et al do not teach a nucleic acid encoding SEQ ID NO:2.

Carlton et al teach that strain HD536 has a 68 MDa plasmid implicated in toxin production (Table 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of cloning delta-endotoxin genes from *B. thuringiensis* plasmids as taught by Ben-Dov et al, to clone delta-endotoxin genes from strain HD536 described in Carlton et al. One of ordinary skill in the art would have been motivated to do so because an increased repertoire of delta-endotoxins would be desirable for increasing toxicity spectra and for

overcoming pest resistance to existing endotoxins. It is obvious to use the 68 MDa plasmid from HD536 because HD536 was known in the art as having a toxin-encoding plasmid (Carlton et al, Table 1). In cloning the toxins from the 68 MDa plasmid from HD536 one of skill in the art would necessarily isolate a nucleic acid encoding SEQ ID NO:2. It would be obvious to one of skill in the art to culture the host cell comprising the plasmid in conditions under which the nucleic acid encoding the toxins is expressed to study the toxicity of the protein, particularly for toxicity to lepidopteran plant pests.

Applicant urges that there would be no reasonable expectation of success in isolating AXMI-007 sequences or of obtaining any toxin genes from HD536 since no insecticidal activity was demonstrated for this strain prior to Applicant's disclosure (response pg 7).

This is not found persuasive because Carlton et al teach that strain HD536 has a 68 MDa plasmid implicated in toxin production (Table 1).

Applicant urges that the evidence described is that when the 68 MDa plasmid is present in the strain it formed crystals, while when it did not no crystals formed and when the plasmid was transferred to a B cereus strain it formed crystals; the presence or absence of a crystals is not a demonstration of having insecticidal activity (response pg 7).

This is not found persuasive. This is not what Carlton et al shows; Carlton et al does not show such data. Carlton et al says HD536 makes a toxin (Table 1). Applicant's representative cannot present data.

Applicant urges that AXMI-007 has low sequence homology to other known toxins, and the probes disclosed in Ben-Dov could not have been used to isolate SEQ ID NO:1 or 3 (response pg 7).

This is not found persuasive because knowledge that the 68 KDa plasmid encodes a toxins would motivate one of skill in the art to sequence the plasmid to search for the toxins genes.

Applicant urges that a chemical structure cannot be considered obvious unless the prior art suggest a lead compound and modifications necessary to achieve the claimed molecule (response pg 8).

This is not found persuasive because no modifications of the lead compound; the HD536 68 kDa plasmid is necessary to achieve the claimed molecule; all that is required is sequencing the plasmid.

Applicant urges that secondary considerations of the advantageousness of the claimed invention, particularly its pesticidal activity, provide additional support for nonobviousness (response pg 8-9).

This is not found persuasive. Applicant has not shown that the toxin provides activity previously shown not to be present in HD536 or present on the 68 kDa plasmid.

6. Claims 2-3, 8-11, 19 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Dov et al in view of Carlton et al as applied to claims 1, 4-7, 24 and 27 above, and further in view of Koziel et al (1997, US Patent 5,625,136). Applicant did not argue this rejection separately from the previous one in the response filed 23 October 2009.

The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 August 2009, as applied to claims 2-3, 8-11, 19, 22-23, 25-26 and 28-29. Applicant's arguments filed 23 October 2009 have been fully considered but they are not persuasive.

The claims are drawn to plants transformed with a nucleic acid encoding a toxin comprising SEQ ID NO:2, including plant optimized nucleic acids.

The teachings of Ben-Dov et al in view of Carlton et al are discussed above. Ben-Dov et al in view of Carlton et al do not teach plants and seeds transformed with the nucleic acid.

Koziel et al teach construction of a Cry endotoxin coding sequence that is designed for expression in a plant; this sequence has increased GC content relative to the native coding sequence (column 7, lines 19-56; column 9, lines 50-56). Koziel et al also teach expression of the modified Cry endotoxin coding sequence in maize cells from a victor that also encodes phosphoenolpyrivate carboxylase (column 59, line 40, to column 63, line 50), as well as maize plants and seeds transformed with the modified Cry endotoxin coding sequence (claims 4-25).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to transform the nucleic acid taught by Ben-Dov et al in view of Carlton et al into plants, including maize, as described in Koziel et al. One of ordinary skill in the art would have been motivated to do so because the resultant plants will be more resistant to insect pests, and the farmer thus less likely to suffer economic loss because of them.

Conclusion

7. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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March 5, 2010

/Anne R Kubelik/
Primary Examiner, Art Unit 1638